

### **REMARKS**

The above amendments to the above-captioned application along with the following remarks are being submitted as a full and complete response to the Official Action dated September 13, 2004. In view of the above amendments and the following remarks, the Examiner is respectfully requested to give due reconsideration to this application, to indicate the allowability of the claims, and to pass this case to issue.

#### **Status of the Claims**

Claims 4-9, 13-15, 18-23, 26-31 and 34-39 are under consideration in this application. Claims 4-7, 15, and 34-39 are being amended, as set forth above, in order to more particularly define and distinctly claim Applicants' invention.

#### **Additional Amendments**

The claims are being amended to correct formal errors and/or to better disclose or describe the features of the present invention as claimed. Applicants hereby submit that no new matter is being introduced into the application through the submission of this response.

#### **Formality Rejection**

Claims 7, 15 and 34-39 were rejected under 35 U.S.C. § 112, second paragraph, for failing to clearly define the subject matter, and claims 4-9, 13-15, 26-31 and 34-39 were rejected under 35 U.S.C. § 112, first, paragraph, for failing to describe the subject matter in such a manner that would enable one skilled in the art to make or use the invention.

Applicants would like to point out that the specification discusses survival ratios in a 250 mM salt treatment in Fig. 3 and on page 19, 15-23 *"It has been shown that the control samples in which proline-related genes have not been introduced die 5 days after a salt treatment, while the transgenic rice samples which accumulate proline show high survival rates, i.e., 95% for the third day, and 65% even after the five-day treatment. This indicates that the salinity tolerance can be improved by transforming rice, and thereby enhancing the proline accumulating ability thereof."* A 132 Declaration regarding survival ratios with respect to the amount of proline amount is concurrently submitted as required by the Examiner, and the claims are being amended as suggested by the Examiner. Accordingly, the

withdrawal of the outstanding informality rejections is in order, and is therefore respectfully solicited.

#### Prior Art Rejections

Claims 4-9, 13-15, 26-31 and 34-39 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhu et al. (Plant Sci. 1998, Vol. 139, pages 41-48; hereinafter "Zhu") in view of Igarashi et al. (Plant Mol. Bio. 1997, Vol. 33, pages 857-865; hereinafter "Igarashi"), Yoshiba et al. (Plant J. 1995, Vol. 7, pages 751-760; hereinafter "Yoshiba"), Rashid et al. (Plant Cell Rep. 1996, Vol. 15, pages 727-730; hereinafter "Rashid") and Shimamoto et al. (Nature, 1989, Vol. 338, pages 274-276; hereinafter "Shimamoto") and Nanjo et al. (FEBS Lett., 1999, Vol. 461, pages 205-210; hereinafter "Nanjo") These rejections have been carefully considered, but are most respectfully traversed.

The transgenic rice plant of the invention, as now recited in claim 4, have introduced in them in sense orientation (p. 11, last line; Fig. 1D): (1) a P5CS gene of rice containing the sequence according to SEQ ID NO. 1, or a P5CS gene of Arabidopsis thaliana containing the sequence according to SEQ ID NO. 2, and then (2) the antisense gene of a ProDH gene of Arabidopsis thaliana containing the sequence according to SEQ ID NO. 3.

The invention is also directed to a transgenic rice plant, as now recited in claim 5, in which have been introduced in sense orientation and tandemly connected to each other: (1) a P5CS gene of rice containing the sequence according to SEQ ID NO. 1, or a P5CS gene of Arabidopsis thaliana containing the sequence according to SEQ ID NO. 2, and then (2) the antisense gene of a ProDH gene of Arabidopsis thaliana, said ProDH gene containing the sequence according to SEQ ID NO. 3.

The invention is also directed to a vector, as now recited in claim 6, in which have been introduced in sense orientation and tandemly connected to each other: (1) a P5CS gene of rice containing the sequence according to SEQ ID NO. 1, or a P5CS gene of Arabidopsis thaliana containing the sequence according to SEQ ID NO. 2, and then (2) the antisense gene of a ProDH gene of Arabidopsis thaliana, said ProDH gene containing the sequence according to SEQ ID NO. 3.

Although the prior art teaches a transgenic rice plant in which introduced "(1) a P5CS gene of rice containing the sequence according to SEQ ID NO. 1, or a P5CS gene of Arabidopsis thaliana containing the sequence according to SEQ ID NO.2, OR (2) the antisense gene of a ProDH gene of Arabidopsis thaliana containing the sequence according to

SEQ ID NO 3", none of the cited references teaches or suggests a transgenic rice plant in which introduced in sense orientation "(1) a P5CS gene of rice containing the sequence according to SEQ ID NO 1, or a P5CS gene of Arabidopsis thaliana containing the sequence according to SEQ ID NO. 2, AND (2) the antisense gene of a ProDH gene of Arabidopsis thaliana containing the sequence according to SEQ ID NO3" as the invention.

Applicants contend that there is no teaching of introducing in sense orientation first the P5CS gene and then the antisense gene of ProDH in a rice plant in any one the cited prior art references. Rather, each reference is limited to introducing just one of P5CS gene and antisense gene of ProDH in a rice plant, not a combination of both.

Neither reference shows any teaching or suggestion for how (1) and (2) are arranged with respect to each other. In the present invention, the choice of connection locations has been specified as (1) and then (2) in sense orientation and tandemly connected to each other to serve the unique purpose of increasing proline accumulation 100 times or more (p. 18, lines 13-22; Fig. 2). One skilled in the art could not make a combination as claimed by the Applicants based on the above prior teachings except by using Applicants' invention as a blueprint. Applicants will point out that a rejection based on hindsight knowledge of the invention at issue is improper.

Although the Examiner asserted that "It is not necessary that a reference actually suggest changes or possible improvements that applicant made. *In re Sheckler*, 58 C.C.P.A. 936, 438 F.2d 999, 1000-01 (Fed. Cir. 1971)," the Federal Circuit explained that exact case law 12 years later in that "*it was not necessary that the prior art suggest expressly or in so many words, the "changes or possible improvements" the inventor made. It was only necessary that he apply "knowledge clearly present in the prior art."* *Sheckler*, 438 F.2d at 1001, 168 U.S.P.Q. (BNA) at 717. (Emphasis supplied.) If this last test is not met, the invention claimed would not have been obvious from the references. *In re Imperato*, *supra*, may be taken as an example of a case when combination of the teachings of prior art references did not suggest the inventor's result. The court therefore reversed the board's holding of obviousness. *In re Sernaker*, 702 F.2d 989, 994, 1983 U.S. App. LEXIS 13565, 217 U.S.P.Q. (BNA) 1 (Fed. Cir. 1983)." Applicants contend that the knowledge of arranging (1) and then (2) in sense orientation and tandemly connected to each other was NOT *clearly present in the prior art*, and the combination of the teachings of prior art references did NOT suggest the inventor's result, i.e., the amount of proline accumulation in the transgenic rice

plant is 100 times or more (p. 18, lines 13-22; 1<sup>st</sup> right column in Fig. 2.) with respect to that of the control samples. As such, the invention is not obvious in view of the prior art.

In addition, the Examiner applied the case law that "The ordinarily skilled artisan is presumed to know more about the art than only what is disclosed in the applied references, and has knowledge apart from the content of the references. *In re Bode*, 550 F.2d 656, 1977 CCPA LEXIS 171, 193 U.S.P.Q. (BNA) 12 (C.C.P.A. 1977)" out of context. *Bode* was applied for expanding the scope of the specification to support enablement, rather than expending the knowledge of one skilled in the art to make an invention obvious. "Every patent application and reference relies to some extent upon knowledge of persons skilled in the art to complement that disclosed in order that it be 'enabling' within the meaning of § 112." See also *In re Bode*, 550 F.2d 656 (C.C.P.A. 1977) ("One skilled in the art would be expected to have sufficient basic knowledge to construct such means, the structure of which would be simple."). As *Bode* makes clear, skill in the art can be relied upon to supplement that which is disclosed as well as to interpret what is written. The *Bode* interpretation of the enabling requirement has deep historical roots. Nearly one century ago, the Supreme Court, in *Loom Co. v. Higgins*, 105 U.S. 580, 585-86, 26 L. Ed. 1177 (1882), similarly construed the predecessor to Section 112. *Rengo Co. v. Molins Machine Co.*, 657 F.2d 535, 549, 1981 U.S. App. LEXIS 11213, 211 U.S.P.Q. (BNA) 303, 60 A.L.R. Fed. 534 (3d Cir. N.J. 1981)."

In the context of obviousness, although the Examiner asserted that "Conclusion of obviousness can be drawn "from common knowledge and common sense of the person of ordinary skilled in the art without specific hint or suggestion in the particular reference. *In re Bozek*, 416 F.2d 1385, 57 C.C.P.A. 713, 163 U.S.P.Q. (BNA) 545 (C.C.P.A. 1969)," the Federal Circuit explained the exact case law 33 years later that "The case on which the Board relies for its departure from precedent, *In re Bozek*, 57 C.C.P.A. 713, 416 F.2d 1385, 163 U.S.P.Q. (BNA) 545 (CCPA 1969), indeed mentions "common knowledge and common sense," the CCPA stating that the phrase was used by the Solicitor to support the Board's conclusion of obviousness based on evidence in the prior art. *Bozek* did not hold that common knowledge and common sense are a substitute for evidence, but only that they may be applied to analysis of the evidence. *Bozek* did not hold that objective analysis, proper authority, and reasoned findings can be omitted from Board decisions. Nor does *Bozek*, after thirty-two years of isolation, outweigh the dozens of rulings of the Federal Circuit and the Court of Customs and Patent Appeals that

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*patentability must be based on evidence. This court has remarked, in Smiths Industries Medical Systems, Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1356, 51 U.S.P.Q.2D (BNA) 1415, 1421 (Fed. Cir. 1999), that Bozek's reference to common knowledge "does not in and of itself make it so" absent evidence of such knowledge. In re Lee, 277 F.3d 1338, 1345, 2002 U.S. App. LEXIS 855, 61 U.S.P.Q.2d (BNA) 1430 (Fed. Cir. 2002)."*

"It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *In re Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d at 1697 (Fed. Cir. 2001) ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings."). While the court explained that, "as an administrative tribunal the Board clearly has expertise in the subject matter over which it exercises jurisdiction," it made clear that such "expertise may provide sufficient support for conclusions [only] as to peripheral issues." *Id.* at 1385-86, 59 USPQ2d at 1697. As the court held in *Zurko*, an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support. *Id.* at 1385, 59 USPQ2d at 1697. See also *In re Lee*, 277 F.3d 1338, 1344-45, 61 USPQ2d 1430, 1434-35 (Fed. Cir. 2002) (In reversing the Board's decision, the court stated " 'common knowledge and common sense' on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. The Board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies."). " As such the Examiner shall provide "some concrete evidence in the record in support of" factual assertion to rely solely on "common knowledge" in the art as the principal evidence.

Under the current case law and MPEP 2144.03, Applicants hereby respectfully assert that the Examiner did not properly rely upon the knowledge of one skilled in the art only based upon concrete evidence in the record in support of the alleged knowledge of one skilled in the art of arranging (1) and then (2) in sense orientation and tandemly connected to each other.

Applicants contend that neither the cited references, nor their combination teaches or discloses each and every feature of the present invention as disclosed in independent claims

4-6. As such, the present invention as now claimed is distinguishable and thereby allowable over the rejections raised in the Office Action. The withdrawal of the outstanding prior art rejections is in order, and is respectfully solicited.

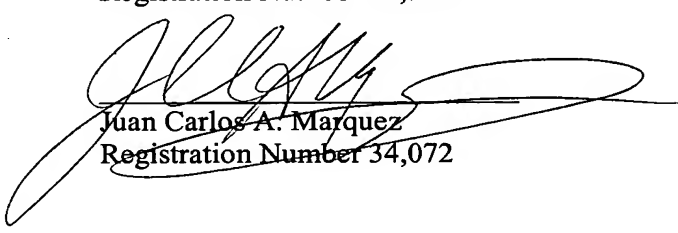
Conclusion

In view of all the above, clear and distinct differences as discussed exist between the present invention as now claimed and the prior art references upon which the rejections in the Office Action rely, Applicants respectfully contend that the prior art references cannot anticipate the present invention or render the present invention obvious. Rather, the present invention as a whole is distinguishable, and thereby allowable over the prior art.

Favorable reconsideration of this application is respectfully solicited. Should there be any outstanding issues requiring discussion that would further the prosecution and allowance of the above-captioned application, the Examiner is invited to contact the Applicants' undersigned representative at the address and phone number indicated below.

Respectfully submitted,

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